



DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL MATERIEL AGENCY
1423 SULTAN DRIVE, SUITE 100
FORT DETRICK, MARYLAND 21702-5001

REPLY TO
ATTENTION OF:

MCMR-MMR-OC

22 February 2005

**EXECUTIVE SUMMARY (EXSUM)
STANDARD OPERATING PROCEDURES (SOP)**

1. PURPOSE: To provide procedural guidance on how to prepare an Executive Summary (EXSUM) that addresses the prominent facts and circumstances when an activity suspects the vaccine has become compromised.

2. APPLICABILITY: The procedures contained herein are applicable to all Department of Defense (DoD) activities receiving the Anthrax, Smallpox and Influenza vaccines.

3. EXSUM REQUIREMENTS:

a. DoD Activities are required to prepare an EXSUM when it is suspected, that there is a potential loss of vaccine efficacy (i.e. exceeding required storage temperature parameters 2°C to 8°C).

b. Must be prepared in memorandum format (no longer than one page in length) and submitted to the United States Army Medical Materiel Agency (USAMMA), Distribution Operations Center (DOC) within 24 hours upon discovery of potentially compromised vaccine.

c. The EXSUM must be routed up the chain of command for review and endorsement before faxing to the USAMMA/DOC.

d. An EXSUM is not required for vaccine that has reached its expiration date. (See Destruction SOP for disposal)

4. HOW TO PREPARE AN EXSUM: The EXSUM must contain the following information

- a. Explain in detail the circumstances surrounding the potential loss of vaccine potency.
- b. Location in which the vaccine was discovered.
- c. Temperature of the location in which the vaccine was discovered.
- d. List of Lot number(s) affected.
- e. Number of un-opened vial(s).
- f. Detailed explanation of corrective action to preclude future losses of vaccine.
- g. Points of Contact (POC) information to include phone number(s)

5. UPON RECEIPT OF THE EXSUM: Once the EXSUM is received at USAMMA/DOC the USAMMA Pharmacy Consultant will review and provide further guidance on the use or disposition of the suspected compromised vaccine.

6. REPLACEMENT OF VACCINE: The DOC must receive the EXSUM from the activities that have identified the potential loss of vaccine efficacy prior to shipping replacement product.

7. FAX: EXSUM's should be sent via fax to the following location:

U.S. ARMY (Executive Agent)

USAMMA Distribution Operations Center (DOC)

COM: (301) 619-4318/7235/3017 DSN 343 - xxxx

FAX: DSN 343-4468 COM: 301-619-4468

EMAIL: USAMMADOC@amedd.army.mil

8. QUESTIONS OR CONCERNS: Those charged with the preparation of the EXSUM should address all questions or concerns to USAMMA Pharmacist/COR: DSN 343-4307/4317 or (301)-619-4307/4317, FAX x4468.

Any proposed changes or updates to this SOP must be brought to the attention of the Distribution Operations Center (DOC), UNITED STATES ARMY MEDICAL MATERIEL AGENCY (USAMMA).